Dated: October 9, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–26325 Filed 10–15–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Electroencephalogram and Event-Related Potential Intermediate Phenotypes for Alcoholism in a Low Prevalence American Indian Tribe

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, regarding the opportunity for public comment on proposed data collection projects, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection Title: Electroencephalogram (EEG) and Event-Related Potential (ERP) intermediate phenotypes for alcoholism in a low prevalence American Indian tribe. Type of Information Collection Request: New. Need and Use of Information Collection: An extensive data set has already been collected by the Laboratory of Neurogenetics, NIAAA, on 294 members of a Southeastern American Indian tribe. We propose to re-contact these individuals to collect additional information. Approximately 100 of the original participants were originally selected as a representative sample of the population. The remaining 194 individuals are family members of alcoholic probands from the population sample. We propose to expand the study to collect (a) measures of intermediate phenotypes for alcoholism and (b) survey-based selected personality characteristics from the same tribal members. Intermediate phenotypes are biological traits that may be influenced by variation at fewer genes and may mediate different aspects of the disease. The intermediate phenotype measurements that we will collect include resting EEG phenotypes (low voltage alpha (LVA) and beta spectral power), ERPs and heart rate variability (HRV). LVA has been found to be more abundant in alcoholics with co-morbid anxiety disorders. Increased beta power has been associated with increased risk of relapse. P300 ERP amplitude is reduced in alcoholics and their alcohol-naïve children. HRV is a potential intermediate phenotype for alcoholism and major depression. We also propose to administer the Temperament and Character Inventory, a standard, survey-based measure of harm avoidance, novelty seeking, reward dependence, and persistence. The use of such intermediate phenotypes and personality measures is likely to increase our ability to find vulnerability genes for alcoholism. We will use these EEG and EKG intermediate phenotypes and personality dimensions in (1) candidate gene analyses and (2) linkage analyses, utilizing the existing DNA, in order to determine the genes that increase an individual's risk for alcoholism and anxiety disorders.

The re-recruitment of the original study participants will start in spring 2003. The study is expected to run for 6 months. Frequency of response: Once per respondent. Affected Public: Individuals. Type of Respondents: Adult members of the Southeastern American Indian tribe who were participants in the original study.

The reporting burden is as follows: Estimated Number of Respondents: It is estimated, after a survey by tribal members, that we will be able to re-recruit approximately 280 of the 294 original participants. Estimated Number of Responses per Respondent" One response per respondent. Average Burden Hours per Response: Three hours per individual, for a total respondent burden of 840 hours. Estimated Total Annual Burden Hours Requested: 840 hours. There are no Costs to Respondents to report. There are no Capital Costs to report. There are no Operating or Maintenance costs to report.

Request for Comments: Written comments and suggestions from the public and affected agencies are invited on the following points: (1) Whether the data collection is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Mary-Anne Enoch M.D., NIH/NIAAA/DICBR/LNG, 12420 Parklawn Drive, Park 5 Building, Room 451, MSC 8110, Bethesda, MD 20892–8110, or e-mail your request to: *maenoch@niaaa.nih.gov.* Dr. Enoch can be contacted by telephone at 301–496–2727.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 7, 2002.

Stephen Long,

Executive Officer, NIAAA.

[FR Doc. 02–26212 Filed 10–15–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on August 5, 2002, page 50679–50680 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Extended Lung Cancer Incidence Follow-Up for the Mayo Lung Project Participants. *Type of Information Collection Request:* EXTENSION, OMB No. 0925–0496, expiration date 10–31–2002. *Need and Use of Information Collection:* The Mayo Lung Project (MLP) was an NCI-funded randomized controlled trial (RCT) of lung cancer screening

conducted among 9,211 male smokers from 1971 to 1983. No reduction in lung cancer mortality was observed in the MLP with an intense regimen of x-ray and sputum cytology screening. Recent analysis of updated mortality and case survival data (through 1996) suggests that lesions with little-to-no clinical relevance (over-diagnosis) may have been detected through screening in the MLP intervention arm. Over-diagnosis leads to unnecessary medical interventions, including diagnostic and treatment procedures that carry with them varying degrees of risk. Consequently, over-diagnosis can result in considerable harm, including premature death, that would not have occurred in the absence of screening. The persistence, after screening ends, of an excess of lung cancer cases in the intervention arm is the strongest evidence in support of over-diagnosis, but this information cannot be adequately obtained with available MLP data. Therefore, we propose to re-contact the MLP participants and/or their next-of-kin to determine the participants who were diagnosed with lung cancer after the formal end of the Project. These data will allow the NCI to either more-convincingly state or perhaps refute the possibility of over-diagnosis in lung cancer screening, and may be used to guide future research agendas and lung cancer screening policies. *Frequency of response:* Once. *Affected public:* Individuals. *Type of respondents:* MLP participants or their next-of-kin. The annual reporting burden is as follows: *Maximum number of respondents:* 6,223; *Estimated number of Responses per Respondent:* 1. *Average Burden Hours Per Response:* 0.25; *Estimated Maximum Total Annual Burden Hours Requested:* 1,556. The annualized cost to respondents is estimated at zero. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the colletion of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20530, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Pamela Marcus, Epidemiologist, Biometry, Research Group, Division of Cancer Prevention, National Cancer Institute, Suite 3131 EPN, 6130 Executive Blvd, Bethesda, MD 20892–7354; or call non-toll free 301–496–7468; or e-mail *pm145q@nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: October 7, 2002.

Reesa L. Nichols,

NCI Project Clearance Liaison.

[FR Doc. 02–26213 Filed 10–15–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications and issued patents listed below may be obtained by contacting Peter A. Soukas, J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 268; fax: 301/402–0220; e-mail: *soukasp@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Novel Spore Wall Proteins and Genes From Microsporidia

J. Russell Hayman, John T. Conrad, Theodore Nash (NIAID)
DHHS Reference No. E–125–01/0
Filed 04 Dec 2001

Microsporidia are obligate intracellular organisms that infect a wide variety of animals ranging from insects and fish to mammals, including humans. Of over 1,000 microsporidial species identified, at least 13 are known to infect humans. The species most commonly identified in humans are members of the families Encephalitozoonidae and Enterocytozoonidae. In humans, microsporidiosis is most often found in HIV/AIDS patients and commonly results in severe diarrhea and wasting. However, microsporidiosis also occurs in immunocompetent individuals and common farm animals. The disease is transmitted via environmentally resistant spores.

This invention claims two spore wall constituents (SWP1 and SWP2) from the microsporidian *Encephalitozoon intestinalis* and the genes from which these two proteins are derived. Further claimed are methods of diagnosing and treating microsporidiosis in a subject. Also claimed are methods for producing an immunoprotective response in a subject. SWP1 is expressed on the surfaces of developing sporonts and SWP2 is expressed on the surfaces of fully formed sporonts. Therefore, they should be exposed to the host cell environment. Based on this theory, antibody responses to SWP1 and SWP2 were addressed in an in vivo mouse model. Immunoprecipitation and Western blot analyses indicated that SWP1 and SWP2 are immunogenic in mouse infections.

This invention is further described in Hayman *et al.*, ''Developmental expression of two spore wall proteins during maturation of the microsporidian *Encephalitozoon intestinalis*,'' *Infect. Immun.* 2001 Nov;69(11):7057–66.

Method for Determining Sensitivity to a Bacteriophage

Carl R. Merril (NIMH), Sankar Adhya (NCI), Dean M. Scholl (NIMH)
DHHS Reference No. E–318–00/0
Filed 23 Jan 2002